



MAR 11 2005

Mr. Gordon M. Walker  
General Counsel  
Nature's Way Products, Inc.  
1375 N. Mountain Springs Parkway  
Springville, Utah 84663

Dear Mr. Walker:

This is in response to your letter of January 27, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that the product Vitamin E Tocotrienols will use the claim "[S]hown to support healthy low-density lipoproteins [sic] (LDL) levels...."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, because the claim you are making for this product represents that the product is intended to affect blood cholesterol (i.e., as LDL; low-density lipoprotein is, by definition, a lipoprotein that transports cholesterol in the blood that is composed of a moderate amount of protein and a large amount of cholesterol) but does not also include a statement about it being intended to affect blood cholesterol that is already in the normal range, it is an implied disease claim.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to

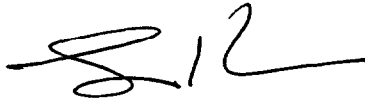
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regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. J. Walker', with a stylized flourish at the end.

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Denver District Office, Office of Compliance, HFR-SW240



January 27, 2005

Office of Nutritional Products Labeling and Dietary Supplements  
Division of Compliance and Enforcement  
Dietary Supplements Branch (HFS-810)  
Food and Drug Administration  
200 "C" St. S.W.  
Washington, D.C. 20204

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To Whom It May Concern:

Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement which bears a statement under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act.

The dietary supplement for which the statement is made is Vitamin E Tocotrienols. The dietary ingredients that are the subject of the statement are Vitamin E and Vitamin E Tocotrienol Complex. The statement reads as follows:

"Vitamin E Tocotrienols is derived from fruits of palm and contains all four isomers which have been shown to support healthy low-density lipoproteins (LDL) levels, which supports cardiovascular health."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

The information contained in this notice is complete and accurate and the above statement is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

A handwritten signature in black ink, appearing to read "Gordon M. Walker".

Gordon M. Walker  
General Counsel

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